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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/216,538	03/23/94	GOELET	P 639103CIP

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18M2/1217

EXAMINER	
SISSON, B	
ART UNIT	PAPER NUMBER
1807	14

DATE MAILED: 12/17/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents



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SERIAL NUMBER 53	FILING DATE 23/94	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

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GIBSON, B EXAMINER	
ART UNIT	PAPER NUMBER
12/10/96	

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/216,538	03/28/94	GOELDT	3310331P

18M2/1210

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SILSON B EXAMINER	
ART UNIT 07	PAPER NUMBER
1/24/10/96	

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/216,538

Applicant(s)

Goelet et al.

Examiner

Bradley L. Sisson

Group Art Unit

1807

☒ Responsive to communication(s) filed on Dec 1, 1995

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 30-38 and 40-46 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 30-38 and 40-46 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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DETAILED ACTION

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

2. The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Attention is directed to page 15, line 17; page 33, lines 25-28, and page 34, lines 5-8, where "PCT Application WO92/15712" is incorporated by reference as teaching an "especially preferred method" of exploiting the oligonucleotide diagnostic assay. Additional basis for requiring the amendment of the specification can be found in applicant's response of December 1, 1995 where at

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paragraph II representations are made that the PCT document provides the needed definitions of terms, e.g., "genetic bit analysis."

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification, as filed, fails to provide sufficient antecedent support for the definition and substeps of "genetic bit analysis" now recited in the claims; see claim 31.

4. The disclosure is objected to because of the following informalities: The specification does not reflect the current status of the following cited applications: (i) Serial No. 08/145,145 at page 1 (said application was abandoned 11 January 1996); and Serial No. 08/005,061 at page 51, line 17 (application was abandoned 24 June 1994).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In order to practice the claimed method, one of skill in the art first needs to identify "a single nucleotide present at a polymorphic site of an equine single nucleotide polymorphism" that is "present in more than 51% of a set of reference humans." The disclosure fails to provide evidence which would reasonably support the position that single nucleotide polymorphisms that are found in horses are in any way

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correlative with humans. The specification does make representations that single nucleotide polymorphism have been found in both humans and horses. The specification has not taken the study to the next level- how correlative are equine systems and human or primate systems such that some reasonable extrapolation could be made. Rather than provide such essential guidance, one is left to "use said determination of subset (ii) to determine whether said target human will have said particular trait." Note, it is not at all clear just what constitutes or even is/are the traits that could be imposed. In order to unravel these mysteries, one of skill in the art, who is on par with those with a Ph.D., or better, would have to resort to blind guessing as to what might one day be correlative. Such efforts would be on the level of years of experimentation with little if any reasonable expectation of success. While suggestions have been made that a possible correlation may exist, such statements do not rise to the level of enablement. Rather, such statements constitute only an invitation to experiment.

6. Claims 33, 34, 37, and 40- 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 33 and 34 recite the limitation "said interrogated single nucleotide polymorphism" in line 1 and line 3, respectively. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 37 recites the limitation "said trait" in line 3. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 40 and 41 depend from canceled claim 39.

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10. Claim 42 recites the limitation "said particular trait" in step (iii), lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 is indefinite with respect to just what constitutes "using" as found in the phrase "using said determination of substep (ii)" (emphasis added).

11. Claims 40 and 41 are rejected under 35 U.S.C. 112, fourth paragraph, for failing to further limit a preceding claim. Claims 40 and 41 depend from canceled claim 39.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Goelet et al. (Goelet).

Claim 30 requires that a genomic DNA fragment be isolated, sequencing of the DNA fragment be performed so to determine primers capable of mediating amplification of the specified fragment; amplification of the DNA wherein said primers are used; determining the sequence of nucleotides of the amplified product; and comparing the sequence of the amplified DNA with that of a reference organism so to identify a nucleotide polymorphic site.

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Goelet, page 1, lines 21-26, states that "Many techniques have been developed...to compare homologous segments of nucleic acid sequence to determine if the segments are identical or if they differ at one or more nucleotides;" this meets the limitation of identifying a "polymorphic site." Pages 10-12 describe additional embodiments where primers are used, along with chain terminators (dideoxynucleotides) in an amplification reaction (polymerase chain reaction; PCR). Page 12, third paragraph, states in part that "[e]ach specific position in the nucleic acid of interest is determined using a different primer. The identity of each nucleotide base or bases at each position can be determined individually or the identities of the nucleotide bases at different positions can be determined simultaneously. The aspect of using primers that hybridizes to the target nucleic acid speaks to there being an isolation and sequence determination of the target nucleic acid such that primers can be developed and used.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

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contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 31, 33-38, 40, 41, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goelet et al., (Goelet).

Goelet, page 1, lines 21-26, states that "Many techniques have been developed (1) to determine the presence of specific nucleic acid sequences, and (2) to compare homologous segments of nucleic acid sequence to determine if the segments are identical or if they differ at one or more nucleotides;" this meets the limitation of identifying a "polymorphic site." Pages 10-12 describe additional embodiments where primers are used, along with chain terminators (dideoxynucleotides) in an amplification reaction (polymerase chain reaction; PCR); see also page 10, third paragraph (limitation of claim 31, step (D)(a) and claim 41). Page 12, third paragraph, states in part that "[e]ach specific position in the nucleic acid of interest is determined using a different primer. The identity of each nucleotide base or bases at each position can be determined individually or the identities of the nucleotide bases at different positions can be determined simultaneously." The aspect of using primers that specifically hybridize to target nucleic acid speaks to there being an isolation and sequence determination of the target nucleic acid such that primers can be developed and used. Page 8, second paragraph states: "The present invention permits analysis of nucleic acid sequences that can be useful in the diagnosis of infectious diseases, the diagnosis of genetic disorders, and in the

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identification of individuals and their parentage" (claims 35-38). Such language speaks to the determination of whether a given polymorphism is or is not present in the target nucleic acid.

Goelet, page 12 states in part that a method is provided for such that one can identify different alleles in a sample which comprises identifying the base or bases present at each of one or more specific positions. Page 30, penultimate paragraph, bridging to page 31, first paragraph, teaches determining the presence or absence of different alleles in a given sample. Page 12, last paragraph, bridging to page 13, first paragraph, provides a method for determining the phenotype of an organism at one or more particular genetic loci. The aspect of determining the alleles and genotype that are present in a given organism's DNA speaks directly to the identification of the source of the nucleic acid as well as the formulation of a genetic map of target nucleic, which, by extension, is the formulation of a genetic map of a given individual; claim 35-37.

Page 34 teaches coupling primers to a solid support, e.g., beads; claim 40.

Goelet does not teach explicitly of "reference human;" however, the aspect of having a "reference" is reasonably suggested as the method taught require that a comparison be made, be it between different organisms as to the presence of different alleles or genetic loci, as well as determining whether a given individual is the parent of another. Clearly, such methods require a comparison to be made.

In view of the foregoing prior art teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the presence or absence of given single nucleotide at a polymorphic region of a human single nucleotide polymorphism where such

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determination was performed through the primer extension reaction which incorporated an optionally detectably labelled chain-terminating moiety, e.g., a dideoxynucleotide. Given the explicit teaches to this end and the guidance provided for establishing the likelihood of a parental relationship between two individuals, said ordinary artisan would have had a reasonable expectation of success. Therefore, and in the absence of convincing evidence to the contrary, the claimed method is *prima facie* obvious in view of the prior art of record.

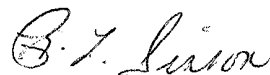
Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


BRADLEY L. SISSON
PATENT EXAMINER
GROUP 1800

12-1-96